Award Number: W81XWH-08-1-0739

TITLE:

A Randomized Controlled Study of Mind-Body Skills Groups for Treatment of War-Zone Stress in Military and Veteran Populations

PRINCIPAL INVESTIGATOR:

James S. Gordon, MD; Madeline Uddo, PhD, Julie K. Staples, PhD, Michelle Hamilton, PhD

CONTRACTING ORGANIZATION:

The Center for Mind-Body Medicine

Washington, DC 20015-1813

REPORT DATE:

October 2010

TYPE OF REPORT:

Annual

PREPARED FOR: U.S. Army Medical Research and Materiel Command Fort Detrick, Maryland 21702-5012

DISTRIBUTION STATEMENT:

Approved for public release; distribution unlimited

The views, opinions and/or findings contained in this report are those of the author(s) and should not be construed as an official Department of the Army position, policy or decision unless so designated by other documentation.

Form Approved REPORT DOCUMENTATION PAGE OMB No. 0704-0188 Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing this collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to Department of Defense, Washington Headquarters Services, Directorate for Information Operations and Reports (0704-0188), 1215 Jefferson Davis Highway, Suite 1204, Arlington, VA 22202-4302. Respondents should be aware that notwithstanding any other provision of law, no person shall be subject to any penalty for failing to comply with a collection of information if it does not display a currently valid OMB control number. PLEASE DO NOT RETURN YOUR FORM TO THE ABOVE ADDRESS. 1. REPORT DATE (DD-MM-YYYY) 2. REPORT TYPE 3. DATES COVERED (From - To) 25 Sep 2009 - 24 Sep 2010 01-10-2010 Annual 4. TITLE AND SUBTITLE 5a. CONTRACT NUMBER A Randomized Controlled Study of Mind-Body Skills Groups for **5b. GRANT NUMBER** W81XWH-08-1-0739 Treatment of War-Zone Stress in Military and Veteran **5c. PROGRAM ELEMENT NUMBER Populations** 6. AUTHOR(S) 5d. PROJECT NUMBER Gordon, James S; Staples, Julie K; Uddo, Madeline; Hamilton, Michelle 5e. TASK NUMBER 5f. WORK UNIT NUMBER 7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) 8. PERFORMING ORGANIZATION REPORT NUMBER The Center for Mind-Body Medicine Washington, CC 20015-1813 9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES) 10. SPONSOR/MONITOR'S ACRONYM(S) U. S. Army Medical Research and Materiel Command Fort Detrick, Maryland 21702-5012 11. SPONSOR/MONITOR'S REPORT NUMBER(S) 12. DISTRIBUTION / AVAILABILITY STATEMENT Approved for public release, distribution unlimited 13. SUPPLEMENTARY NOTES 14. ABSTRACT The purpose of the project is to evaluate the hypotheses that participation in a mind-body skills group program by veterans who have experienced a stressful war-related situation and have symptoms of posttraumatic stress disorder (PTSD) will significantly: (1) decrease symptoms of PTSD; (2) decrease feelings of anger; (3) improve quality of sleep; (4) decrease symptoms of depression and anxiety; (5) increase posttraumatic growth; and (6) increase quality of life, as compared to a standard treatment control group. This report describes the progress on this project to date. The protocol has now been approved by the Institutional Review Boards. All of the group leaders who will be facilitating the mind-body skills group intervention have co-facilitated groups under the supervision of the clinical director and are fully trained. Participants are being recruited and are being screened by the research coordinator for enrollment.

15. SUBJECT TERMS

1. Mind-Body Therapies; 1. Stress Disorders, Post Traumatic; 3. Brain Injuries; 4. Depressive Disorder; 5. Anxiety Disorders; 6. Anger;

7. Sleep Disorders

16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON USARMC
a. REPORT U	b. ABSTRACT U	c. THIS PAGE U	UU	5	19b. TELEPHONE NUMBER (include area code)

Table of Contents

<u>Page</u>	<u> </u>
Introduction 1	
Body1	
Key Research Accomplishments2	
Reportable Outcomes2	
Conclusion2	
References2	
Annendices 2	

Introduction:

The subject of the research is a randomized controlled study of mind-body skills groups for treatment of war zone stress in military and veteran populations. The purpose of the research is to determine whether participation in mind-body skills groups by veterans, who have experienced a deployment-related criterion A stressor and are reporting PTSD symptoms, will result in improvement in symptoms of PTSD, depression, and anxiety, and will reduce anger, improve quality of life, quality of sleep, and result in posttraumatic growth. The scope of the research involves the randomization of 160 veterans meeting the criteria for inclusion to participate in either an intervention group, consisting of a series of mind-body skills groups, or a control group, consisting of standard treatment. The mind-body skills group intervention consists of groups of 8-10 participants. The mind-body skills groups will include the teaching and practice of meditation, guided imagery, and breathing techniques; self-expression through words, drawings and movement; autogenic training and biofeedback; and genograms. The groups will be held for 10 two hour sessions either on alternate Saturdays (2 sessions per Saturday) or once a week with additional groups 1, 3, and 6 months later. Pre and post measurements using questionnaires to measure each of the outcomes will be administered. The questionnaires will be administered again at 6 month follow-up.

Body:

As noted in previous reports, this project has undergone significant delays due to the regulatory process including the VA requirement for Drs. Gordon and Staples to be hired as without compensation (WOC) employees and the need to go through an additional IRB approval as a result of securing our own FederalWide Assurance (FWA). These delays were outlined in detail in our last annual report. The protocol has now been approved by the VA Institutional Review Board (IRB) and Western IRB, the IRB of record for the FWA. We are now completing tasks that were outlined for the end of last year and are described below.

The following tasks were outlined in the second half of the first year (April 2009 to September 2009):

- 1. Participants will be recruited as described in the project narrative and screened for inclusion/exclusion criteria by the research coordinator.
- 2. The clinical director will supervise the trained group leaders who will be facilitating the mind-body skills group intervention.
- 3. The mind-body skills groups will begin on alternate Saturdays for 5 weeks or weekly evening groups with a one week make-up session.
- 4. Baseline and post data will be collected prior to, and after, participation in the mind-body skills groups and at the same time points for the treatment as usual (TAU) control groups.
- 5. Data will be scanned and entered after the post intervention data is collected.

The tasks outlined for October 2009 to September 2010 were the same as above in addition to:

1. Six month follow-up data will be collected for the intervention and control groups.

Of the above tasks, participants are now being recruited and are being screened for enrollment by the research coordinator. All of the group leaders who will be facilitating the mind-body skills group intervention have co-facilitated groups under the supervision of the Center for Mind-Body

Medicine's clinical director and are fully trained. Once enough participants are enrolled, they will be randomized and the intervention will begin.

Key Research Accomplishments:

Because the actual research portion of the project has not yet begun for the reasons discussed above, there are no key research accomplishments to report at this time.

Reportable Outcomes:

There are no specific reportable outcomes for this year.

Conclusion:

There are no results to summarize to date.

There are no references, appendices, or supporting data at this time.